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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,596	12/07/2001	Michael M. Becker	GP123-02.UT	6565
21365 7590 01/30/2008 GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE Mail Stop #1 / Patent Dept. SAN DIEGO, CA 92121			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER
			NOTIFICATION DATE 01/30/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com  
kelleec@gen-probe.com  
belindao@gen-probe.com

<b>Interview Summary</b>	Application No.	Applicant(s)	
	10/020,596	BECKER, MICHAEL M.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

All participants (applicant, applicant's representative, PTO personnel):

(1) Bradley L. Sisson. (3) \_\_\_\_\_

(2) Charles B. Capellari. (4) \_\_\_\_\_

Date of Interview: 14 January 2008.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Draft version of proposed new claim 62 submitted via email on January 8 and 14, copy attached.

Claim(s) discussed: 62.

Identification of prior art discussed: WO 91/08480 (Pontius).

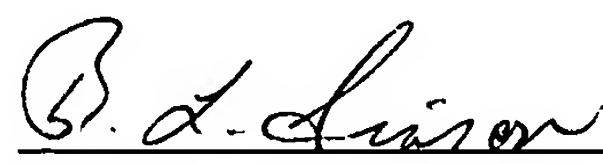
Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Mr. Sisson noted that Pontius uses a secondary binding pair to accelerate the binding of a primary binding pair wherein the primary binding pair can be complementary nucleic acids. The aspect of how the secondary binding pair members were being introduced and used was discussed. While Pontius does disclose the coupling of the secondary binding pair members to that of the primary binding pair members, Pontius, at page 20, last paragraph, also teaches that such coupling does not necessarily have to take place, that the coupling can be by non-covalent means, and that only one of the members of the secondary binding pair needs to be coupled to a member of the primary pair "at most times." Mr. Sisson indicated that such language clearly suggests that one member of the secondary binding pair need not be bound to a member of the primary binding pair, and that even the second member of the secondary binding pair does not have to be coupled continuously to a member of the primary binding pair.

Mr. Sisson indicated that the addition of the second member of the secondary binding pair could constitute the "dissociation reagent" as the members of the secondary binding pair have a higher coefficient of association than do the member of the primary binding pair (Pontius at page 2, bridging to page 3). Mr. Sisson noted that with one member of the secondary binding pair not having to be associated with either member of the primary binding pair, and the remaining member of the secondary binding pair only having to be associated with a member of the primary binding pair part of the time (Pontius at page 20), it becomes a question as to just when the second (uncoupled) member of the secondary binding pair is added to the reaction mixture, which is arguably a matter of routine optimization.

Motivation for using a secondary pair in combination with a primary binding pair can be found at page 3 of Pontius where Pontius teaches that a preferred embodiment of a primary binding pair is found in complementary nucleic acids. Also disclosed is a 10 to 100 fold increase in the rate of binding of the members of the primary binding pair when the secondary binding pair is present.

## Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**  
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner.  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Sisson, Bradley**

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**From:** Cappellari, Chuck [ChuckCa@gen-probe.com]  
**Sent:** Tuesday, January 08, 2008 3:24 PM  
**To:** Sisson, Bradley  
**Subject:** Proposed Claims for Serial No. 10/020,596  
**Attachments:** Proposed Claim 62 010808.rtf

Dear Examiner Sisson,

Attached are alternative proposals for new independent claim 62 in order of preference. Please let me know if any of these is acceptable to you and if you have any suggested changes. As we discussed this morning, support for the amended language can be found in the specification at, for example, page 35, line 24 *et seq.*

Thank you for your willingness to consider these proposed claims.

Best regards,

Chuck

<<Proposed Claim 62 010808.rtf>>

**Charles B. Cappellari**

Senior Patent Counsel

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**Alternative Proposals for New Independent Claim 62 in Serial No. 10/020,596**

62. In a method of detecting in a sample a hybridization complex formed between a labeled polynucleotide probe and a target nucleic acid in the presence of a polycationic polymer provided to the sample in an amount sufficient to increase the rate at which the complex is formed, the improvement comprising providing to the sample a dissociating reagent in an amount sufficient to dissociate the polymer from the complex after the probe and the target nucleic acid have had sufficient time to associate in the sample, and detecting the complex in the presence of unhybridized probe after the dissociating reagent has been provided to the sample.

62. In a [[method of]] homogenous assay for detecting in a sample a hybridization complex formed between a labeled polynucleotide probe and a target nucleic acid in the presence of a polycationic polymer provided to the sample in an amount sufficient to increase the rate at which the complex is formed, the improvement comprising providing to the sample a dissociating reagent in an amount sufficient to dissociate the polymer from the complex after the probe and the target nucleic acid have had sufficient time to associate in the sample, and detecting the complex after the dissociating reagent has been provided to the sample.

62. In a [[method of]] homogenous assay for detecting in a sample a hybridization complex formed between a labeled polynucleotide probe and a target nucleic acid in the presence of a polycationic polymer provided to the sample in an amount sufficient to increase the rate at which the complex is formed, the improvement comprising providing to the sample a dissociating reagent in an amount sufficient to dissociate the polymer from the complex after the probe and the target nucleic acid have had sufficient time to associate in the sample, and detecting the complex in the presence of unhybridized probe after the dissociating reagent has been provided to the sample.



**Sisson, Bradley**

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**From:** Cappellari, Chuck [ChuckCa@gen-probe.com]  
**Sent:** Monday, January 14, 2008 5:10 PM  
**To:** Sisson, Bradley  
**Subject:** U.S. Application No. 10/020,596 / Gen-Probe Docket No. GP020-02.UT

Dear Examiner Sisson,

Below is a newly proposed claim 62 based on your comments this morning.

62. In a method of detecting in a sample a hybrid formed between a labeled polynucleotide probe and a target polynucleotide in the presence of a polycationic polymer provided to the sample in an amount sufficient to increase the rate at which the hybrid is formed, the improvement comprising providing to the sample a dissociating reagent in an amount sufficient to weaken bonds formed between the polynucleotides and the polycationic polymer after the probe and the target polynucleotides have had sufficient time to associate in the sample, and detecting the hybrid in the presence of unhybridized probe after the dissociating reagent has been provided to the sample.

Also, I had a chance to take a look at the sections of the Pontius document you referred to and believe that there are grounds for distinguishing the teachings of Pontius from the claimed invention. In Pontius, members of the secondary binding pair are attached to members of the primary binding pair to enhance the rate at which the members of the primary binding pair associate in solution. See Pontius at para. bridging pages 2 and 3. Thus, rather than functioning to dissociate a cationic molecule from a complex formed by the members of the primary binding pair, the members of the secondary binding pair function as the accelerant in increasing the rate at which the members of the primary binding pair associate. Therefore, there is no inherent anticipation and no suggestion to use a dissociating reagent to separate the members of the secondary binding pair from the members of the primary binding pair after the complex has formed.

Please let me know if you have any questions or further thoughts.

Best regards,

Chuck

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